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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/039,307

10/26/2001

Michael R.S. Hill

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EXAMINER

OROPEZA, FRANCES P

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/039,307	<b>Applicant(s)</b> HILL ET AL.	
	<b>Examiner</b> FRANCES P. OROPEZA	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/13/08 (RCE and Amendment).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 28-40 and 48-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-27 and 41-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/13/08 has been entered.

2. Newly submitted claims 48-53 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: When compared to independent claim 17, independent claim 48 does not include the limitation of the pacing therapy consists of a cardiac resynchronization therapy.

Since the Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 48-53 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Independent claim 17 was amended, claims 21 and 22 cancelled and claims 41-47 added, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

***Claim Rejections - 35 USC § 103***

4. Claims 17, 18, 20-27, 41, 42, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over “Obel” (U.S. Patent No. 5,199,428 to Obel et al.) and “Collins” (U.S. Patent No. 5,203,326 to Collins) in view of “Limousin” (FR 2 805 469 – A1 / English translation in equivalent U.S Patent No. 6,937,898 to Limousin).

Obel discloses an implantable electrical nerve stimulator/ pacemaker for a human/ mammal, the nerves being automatically stimulated in the region of the thoracic vertebra T2 providing electrical communication and the stimulation coordinated to resynchronization the heart to protect the myocardium (abstract; column 1, lines 15-24; column 3, lines 8-28, 42-45; column 3, line 62 – column 4, line 26; column 5, lines 25-64).

Obel discloses pacing therapy using an anti-tachycardia pacing system (column 9, line 53 – column 10, line 2) and therapy using a back-up pacemaker (104) (column 6, line 66 – column 7, line 25) that can also provide programmable parameters and alternate pacing modes (column 8, lines 49-62). While conducting pacing therapy, the electrical stimulation is adjusted in response to one or more monitored physiological parameters (column 3, lines 8-13, 20-28).

Obel discloses cardiac therapy that decreases cardiac workload (abstract), protects the myocardial cells by reducing the oxygen demand, hence optimizing cardiac output (column 2, lines 9-13), decreases the ischemia and the potentially induced arrhythmias such as brady-arrhythmia and tachycardia (column 2, lines 59-65; column 3, lines 29-33; column 9, lines 53-57), provides pacing therapies to maintain the patient’s heart rhythm within acceptable limits (column 3, lines 8-13), ameliorates myocardial ischemia and

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maintains adequate cardiac rate (column 3, lines 14-15), exerts a tonic effect to slow the heart down and control tachycardia (column 5, lines 5-18), and treats conditions and arrhythmias of a heart associated with coronary artery disease and myocardial insufficiency (column 10, lines 31-35), these therapy outcomes read to improve cardiac performance and efficiency of the patient's heart.

As to claim 22 and improving the balance of a neuro-endocrinological system, it is well known in the art as disclosed in U.S. Patent No. 5,203,326 to Collins (cited as art made of record) that:

- electrical stimulation of the nerves of the autonomic nervous system can be used to control the heart (abstract),
- the autonomic nervous system includes the sympathetic and the parasympathetic nervous systems that regulate activities of the cardiac muscle (heart) and the glands (endocrine system) (column 1, lines 36-39), and
- the autonomic nervous system can be stimulated by the vagal nerve to treat arrhythmias (column 5, lines 5-40; column 5, line 59 – column 6, line 35),

hence Obel is accepted to teach improving of the neuro-endocrinological system.

It is noted the concepts of treating a patient to improve cardiac performance and efficiency of the patient's heart, and to improve balance of a neurological system of the patient amount to an intended use limitations of which Obel et al. performs or is inherently capable of performing.

As to claims 41 and 42, Obel discloses delivering pacing therapy and electrical neural stimulation at the same time. The pacing therapy is controlled by a microprocessor based timing and control circuit such that a previously delivered pacing

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therapy is altered based on the sensed atrial beat (column 3, lines 8-13, 29-33; column 8, lines 49-59).

As to claims 46 and 47, Obel discloses monitoring heart rate and heart rate variability (column 3, lines 11, 44; column 6, lines 54-58).

As discussed in the previous seven paragraphs of this action, Obel discloses the claimed invention except for the pacing therapy being cardiac resynchronization therapy.

Limousin teaches anti-tachycardia pacing therapy using cardiac resynchronization therapy for the purpose of treating and managing ventricular tachycardia. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used cardiac resynchronization therapy in the Obel system in order to provide a pacing therapy mode that is more effective in terminating organized ventricular tachycardia condition than previously known anti-tachycardia pacing therapies, the invention recognizing that shock therapy can be used if the resynchronization therapy is not successful to terminate the tachycardia condition (abstract; figure 1; column 1, lines 11-10, 45-50; column 2, lines 12-21; column 2, line 25 – column 3, line 2; column 4, lines 1-15).

As to the Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*,

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958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Obel teach pacing therapy and neural electrical stimulation to decrease the cardiac work load, optimize the cardiac cycle and cardiac output, and treat arrhythmias (abstract; column 5, lines 12-16). Collins teaches autonomic nervous system stimulation to provide therapy for abnormal heart conditions such as arrhythmias (abstract; column 6, lines 1-35). Limousin teaches cardiac resynchronization therapy to manage arrhythmias such as ventricular tachycardia (abstract). The combination of the three references is deemed appropriate and is deemed to teach the instant invention. The rejection of record stands.

5. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over “Obel” (U.S. Patent No. 5,199,428 to Obel et al.) and “Collins” (U.S. Patent No. 5,203,326 to Collins) and “Limousin” ((FR 2 805 469 – A1 / English translation in equivalent U.S. Patent No. 6,937,898 and Limousin) in view of “Adams” (U.S. Patent No. 5,792,187 to Adams).

As discussed in paragraph 4 of this action, modified Obel discloses the claimed invention except the electrode located external to the patient’s body against the skin.

Adams teaches pain suppression treatment using an electrode (100) located external to the patient’s body on the skin at the spine proximate to the dorsal root sensory ganglia for the purpose of relieving pain associated with the high voltage stimulation. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an electrode located external to the patient’s body in the modified Obel et al. system in order to offer a proven treatment for the pain associated with high voltage shocks so the patient’s pain, apprehension, and anxiety is controlled (abstract;

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figures 4; column 2, lines 48-55; column 3, lines 1-8, 45-48; column 7, lines 11-24).

It is noted both electrical and electromagnetic pain suppression systems are well known in the art, and absent any teaching of criticality or unexpected results merely changing the type of system from an electromagnetic system to an electrical system would be an obvious design choice.

6. Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over “Obel” (U.S. Patent No. 5,199,428 to Obel et al.) and Collins (U.S. Patent No. 5,203,326 to Collins) and “Limousin” ((FR 2 805 469 – A1 / English translation in equivalent U.S. Patent No. 6,937,898 to Limousin) in view of “Sjostrand” (U.S. Patent No. 3,650,277 to Sjostrand et al.).

Obel discloses an apparatus to influence blood pressure, (col. 3 @ 62-64).

As discussed in paragraph 3 of this action and in the previous paragraph, modified Obel discloses the claimed invention except using a sensor to monitor systolic blood pressure.

Sjostrand teaches blood pressure modulation using an atrial systolic blood pressure sensor to determine the level of the blood pressure. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an atrial systolic blood pressure sensor in the modified Obel system in order to have an indication how the stimulation treatment was impacting the blood pressure, so appropriate changes in the treatment could be made to optimize the patient’s blood pressure (abstract; column 4, line 74 – column 5, line 4).



***Statutory Basis***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. Fran's schedule typically is Monday and Tuesday 9AM-7PM EST. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Carl. H. Layno can be reached on (571) 272-4949. Carl's schedule typically is Monday, Wednesday, Friday 9AM-5 PM EST; Tuesday, Thursday 9AM-3PM and 9PM-11PM EST. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Frances P. Oropeza/  
Patent Examiner, Art Unit 3766  
January 3, 2009

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/Carl H. Layno/

Supervisory Patent Examiner, Art Unit 3766